



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,468	03/17/2004	Peter J. Fitzgerald	DYRX-001	5475
24353	7590	02/13/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			AHMED, AAMER S	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,468

Applicant(s)

FITZGERALD ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27, 43-51, 66 and 80-84 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 43-51, 66 and 80-84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Movahed US Publication 2002/0099254.

As to claim 1, Movahed discloses a method for removing an agent from a physiological efferent fluid collection site of a body, the method comprising introducing a non-occlusive aspiration element (page 2 paragraph 37 element 18) to a target site at least proximal to the physiological efferent fluid collection site; and activating the aspiration element when the agent is at least predicted to be present in the target site to selectively remove fluid comprising the agent from the physiological efferent fluid collection site wherein the removed-fluid is not returned to the body.

As to claims 2-10, Movahed teaches that the physiological efferent fluid collection site is a coronary sinus (12) in a human and the agent is a therapeutic or contrast agent.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 22-44, 47, 50 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Movahed in view of Bernard et al US Publication Number 2004/001170.

As to claims 22-44 47, 50 and 80 Movahed discloses a system for selectively removing an agent from a physiological efferent fluid collection site, the system comprising a non-occlusive aspiration lumen having a fenestrated distal end (page 2 paragraph 37 element 18), an aspiration mechanism operatively connected to the non-occlusive aspiration lumen; an actuation controller element for controlling actuation of the aspiration mechanism (103) and wherein the controller (103) element is an adaptive controller element, the aspiration lumen is present in a catheter (18) and comprises an expandable distal tip and an open non-sealable fenestrated distal end.

Movahed fails to explicitly disclose a detector for at least predicting the presence of the agent in the physiological efferent fluid collection site; wherein the detector is located upstream of the non-occlusive aspiration element; Bernard et al discloses a similar system in with a detector (108) for at least predicting the presence of the agent in the physiological efferent fluid collection site; wherein the detector is located upstream of the non-occlusive aspiration element; wherein the system comprises a feedback element from the detector to the actuation controller

element, and wherein the actuation controller element selectively actuates in response to signals from the feedback element (see figure 1).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the system of Movahed by incorporating the detector as taught by Bernard et al in order to better remove contrast agents in the blood.

Claims 45, 46, 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Movahed and Bernard et al in view of Nichols et al U.S. Patent Number 4,753,640.

Movahed and Bernard et al disclose the system as described above in reference to claim 43, but fails to disclose that the elongated tubular structure comprises a sealed distal end, a non-expandable distal end and a fenestrated distal end.

Nichols et al discloses a similar device, which includes an elongated tubular structure with a sealed distal end, a non-expandable distal end and a fenestrated distal end.

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the system of Movahed and Bernard et al by adding the sealable and non-sealable fenestrae as taught by Nichols et al in order to raise the withdrawal threshold, providing for a more positive, highly reliable valve action (Nichols et al col. 6 line 43).

Claims 81-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Movahed and Bernard et al and further in view of MacMahon et al US Publication 2005/0085769.

Movahed and Bernard et al teach the system as described above in reference to claims 80, 22 and 43, but fail to disclose that the detector is a fiber-optic detector.

MacMahon et al discloses a similar system in which the detector is fiber-optic (page 11 paragraph 66).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the system of Movahed and Bernard et al by incorporating the fiber-optic detector as taught by McMahon et al in order to allow for non-contact detection of the contrast agent.

Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Movahed and Bernard et al and further in view of Rioux et al US Publication Number 2004/0167385.

Movahed and Bernard et al disclose a kit comprising a non-occlusive aspiration lumen having a fenestrated distal end (page 2 paragraph 37 element 18), an aspiration mechanism operatively connected to the non-occlusive aspiration lumen; an actuation controller element for controlling actuation of the aspiration mechanism (103) and a detector (Bernard et al 108) for at least predicting the presence of the agent in the physiological efferent fluid collection site; wherein the detector is located upstream of the non-occlusive aspiration element (Bernard et al Figure 1). Movahed and Bernard et al fail to disclose instructions for practicing the method as described above in reference to claim 1.

Rioux et al discloses a similar kit including instructions for practicing a similar method (page 7 paragraph 63).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the kit of Movahed and Bernard et al by incorporating the instructions as taught by Rioux in order to describe the use of the system.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Movahed and Bernard et al and Rioux et al and further in view of MacMahon.

Movahed, Bernard et al and Rioux et al teach the kit as described above in reference to claim 66, but fail to disclose that the detector is a fiber-optic detector.

MacMahon et al discloses a similar system in which the detector is fiber-optic (page 11 paragraph 66).

It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the system of Movahed and Rioux et al and Bernard et al by incorporating the fiber-optic detector as taught by MacMahon et al in order to allow for non-contact detection of the contrast agent.

Response to Arguments

Applicant's arguments with respect to claims 1-7, 22, 26, 27, 43, 49, 50, 52 and 66 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

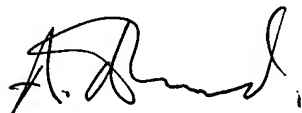
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed


NICHOLAS LUCCHESI
SUPERVISOR
ART UNIT 3763